Remarks

The following remarks are provided in further support of the Claims.

Rejections

Rejection Under 35 U.S.C. §112

Claims 1-11 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is said to be unclear what ismeant by the phrase "columnar structure with self-limiting radial dimension."

With regard to Claim 2, it is unclear whether the claimed diameters pertain only to one particular lipid bilayer molecule of the plurality of lipid bilayer molecules, to all of the plurality of lipid bilayer molecules each having its own diameter which must obtain at least one of the claimed values, or to each of the plurality of lipid bilayer molecules having the same diameter.

With regard to Claim 5, it is unclear what is the relationship of the claimed "mediated by chemical recognition events" of claim 1 to the "ligand promoting adhesion".

With regard to claim 9, it is unclear what is the relationship of the claimed "mediated by chemical recognition events" of claim 1 to the "functionalized with a receptor molecule".

With regard to claims 7 and 8, it is unclear what is the antecedent basis of the phrase "said ligand."

With regard to claim 10, is it unclear what is the antecedent basis of the phrase "said receptor."

Rejection Under 35 U.S.C. §102

Claims 1, 3, 4, 9 and 11 are rejected under 35 U.S.C. §102(b) as being anticipated by Lenk et al. (US 5,925,375).

Claims 1, 3-7, 9 and 11 are rejected under 35 U.S.C. §102(e) as being anticipated by Saflnya et al. (US 6,358,523).

Claims 1-7, 9 and 11 are rejected under 35 U.S.C. §102(e) as being anticipated by Firestone et al. (US 6,537,575).

Claims 1-11 are rejected under 35 U.S.C. §102(a) as being anticipated by Waggoner et al. ("Self-assembled columns..." in JACS 123 (3) 496-7 (2001).

I. DISCUSSION (Rejection Under 35 USC 112)

Claim 1 has been amended to eliminate the unclear language noted in the Office rejection. Applicants concur that the language is unclear and does not further define the phrase "self-assembled".

Claim 2 has been amended to clarify that each of the lipid bilayer molecules has a diameter that is in the stated range.

Claim 5 has been amended to eliminate the unclear language. The phrase "said ligand promoting adhesion between said lipid bilayer molecules" does not further limit the structure but describes a function of the claimed elements and is therefore inappropriate and has been eliminated.

Claims 7 and 8 have been amended to properly provide antecedent basis from claim 5 for "said ligand".

With regard to claim 9, the language of claim 1 "mediated by chemical recognition events" to which a lack of clarity is asserted with respect to the language in claim 9 of "functionallzed with a receptor molecule" has been eliminated. The language of claim 9 now limits the self-assembled lipid bilayer material of claim 1 by requiring functionalization of the lipid bilayer molecules with a receptor molecule as further defined in the Specification (see e.g., page, 4, line 23 through page 6, line 2). 3, and 4 have been amended to recite "flow distribution means", which has sufficient antecedent basis.

Claim 10 has been amended to properly provide antecedent basis from claim 9 for "said receptor".

II. DISCUSSION (Rejection Under 35 USC 102(b), Lenk et al., '375

Lenk et al. teach a multilamellar liposome that contains two or more lipid-containing bilayers. A liposome is a spherical lipid-bilayer material. The invention of Lenk et al. is therefore a spherical structure containing two or more lipid bilayers surrounding the liposome where the bilayers aid in dispersing pharmacological agents. In the present invention, lipid bilayers self-assemble by stacking themselves one upon another in a stacked, columnar structure unlike the invention of Lenk et al. where the lipid bilayers form on a spherical liposome in multiple layers. No liposome is present in the present invention. The lipid bilayers of Lenk et al. do not self-assemble and the diameter of the combined liposome/lipid bilayer spherical structure is dependent upon the diameter of the liposome (as stated in Lenk et al., Column 7, lines 27-31, preferably from about 500 nm to about 1 micron).

Therefore, Lenk et al. does not provide the elements of a plurality of lipid bilayer molecules stacked to form a columnar structure as specified in claim 1, 3, 4, 9 and 11 of the present invention.

II. DISCUSSION (Rejection Under 35 USC 102(e), Safinya et al., '523

Safinya et al. teach charged multilamellar macromolecule-lipid complex comprising lipid layers interspersed with macromolecules (such as DNA). As shown in FIG. 5A of Safinya et al., lipid bilayers are interspersed with macromolecules such as DNA molecules. The lipid bilayer material extends two dimensionally (e.g., laterally) without any set boundaries. In the present invention, lipid bilayer materials self-assemble by stacking themselves one upon another in a stacked, columnar structure. Therefore, the present invention differs from Safinya et al. in that (1) the lipid bilayer materials stack upon one another where Safinya et al. lipid bilayer materials stack on macromolecules and (2) the lipid bilayer materials stack in a columnar structure where the Safinya et al. lipid bilayer materials form a layer of undefined dimensions that extend laterally without a priori bounds.

Therefore, Safinya et al. does not provide the elements of a plurality of lipid bilayer molecules stacked to form a columnar structure as specified in claims 1, 3-7, 9 and 11 of the present invention.

III. DISCUSSION (Rejection Under 35 USC 102(e), Firestone et al., '575

Firestone et al. teach a mixture which is a combination of a lipid, a polymer-grafted phospholipid and a surfactant. The mixture is a gel at certain temperatures and a liquid at other temperature intervals. As depicted in FIG. 3 of Firestone et al., the mixture self-assembles in a micellular arrangement with the lipids, phospholipids and surfactants oriented in a circular fashion. In particular, the lipid materials orient with one end of the lipid molecules along the circular periphery and the other end oriented toward the center of the micelle. The micelles organize into a roughly rod-like or cylindrical structure. Firestone et al. teach a lattice spacing of the liquid phase of several hundred angstroms (e.g., 345 angstroms, Col. 7, line 54) but the cylindrical structure comprising the lattice elements are not lipid bilayer materials stacked one upon another, as taught by the present invention and specified in claim 1 of the present invention. As described above, the cylindrical structures are mixtures of components where the lipid bilayer materials do not stack one upon one another but are oriented in a self-assembled fashion within micelle-like structures in a circular arrangement. In the present invention, lipid bilayer materials self-assemble by stacking themselves one upon another in a stacked, columnar structure.

Therefore, Firestone et al. does not provide the elements of a plurality of lipid bilayer molecules stacked to form a columnar structure as specified in claims 1-7, 9 and 11 of the present invention.

IV. DISCUSSION - 35 USC §102(a) (Waggoner et al) Claims 1-11

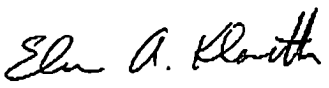
Applicants herewith submit a declaration under 37 CFR §1.132 showing that, to the extent the disclosure in the paper of Waggoner et al. is a disclosure of the present invention claimed in the above-identified patent application, the co-author P. Kotula of the paper was working under direction of the one or more of the inventors of the

Applicants' Invention. Therefore, the cited reference is a publication of Applicants' own invention published less than one year prior to the filing date of the instant Specification and can thereby be removed as a reference according to MPEP 716.10 for rejection of claims 1-11.

CONCLUSION

Applicants have responded to each and every rejection raised by the Office and, in concurrence with the Office, consider that claims 1-17 are now in condition for allowance. Applicants request expeditious processing to issuance. This response is subject to an extension fee charge, as per 37CFR1.17, and should be charged to Charge Account No. 19-0131.

Respectfully submitted,



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